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Notice of Allowability	Application No.	Applicant(s)	
	10/800,215	ROHLEDER ET AL.	
	Examiner	Art Unit	
	Eric F. Winakur	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE and amendment filed 11 May 2007.
2. ☒ The allowed claim(s) is/are 1,2,4-6,8-25 and 27-35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>5/11/07</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles Schmal on 16 May 2007. Applicant agreed to amend claim 34 to include the language used in claim 12.

The application has been amended as follows:

Claim 34 has been amended as follows:

34. The system according to claim 1, wherein:

the sensor head includes a reflective surface [configured and arranged] positioned around the test volume to reflect the Raman-scattered components of the secondary light towards the light receiving surface of the detection light guide; and

the reflective surface is [designed and arranged] positioned to not reflect the primary light emitted from the inbound light guide towards the light receiving surface of the detection light guide.

2. The following is an examiner's statement of reasons for allowance: Applicant cites certain references of relevance on the IDS filed 11 May 2007 which were brought to Applicant's attention by Examiner. The references concern measurement of concentration of physiological constituents of interest with devices that include optical fibers for transmitting and receiving light and selectively permeable membranes, but do

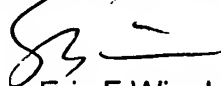
not teach or suggest the claimed apparatus or methods, as set forth in the amended claims. Further, none of the prior art, either alone or in combination, teaches or suggests a system for reagent-free determination of a concentration of an analyte that includes inbound and detection light guides for performing measurements from a test volume, both within a scattered-light percutaneous sensor having a sensor head at its distal end, wherein either a distal end of the sensor head is enclosed by a semipermeable membrane to define the test volume for containing interstitial fluid from tissue and prevent admission of macromolecules having a molecular weight above the exclusion limit of the semipermeable membrane or the sensor head includes a reflective surface positioned around the test volume to reflect Raman-scattered light towards the detection light guide while not reflecting primary light emitted from the inbound light guide towards the detection light guide, in combination with the other claimed elements. Further, the prior art does not teach or suggest a method that includes inserting a sensor head of a percutaneous sensor, the sensor head enclosed by a semipermeable membrane to define a test volume, into skin, and determining concentration of an analyte in the test volume from Raman-scattered components of secondary light, the semipermeable membrane reducing fluorescence interference of the measured signal, in combination with the other claimed steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric F Winakur
Primary Examiner
Art Unit 3768